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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/753,472	01/03/2001	Guilherme Luiz Indig	09820.146	1825
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23524 7590 12/24/2002

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EXAMINER

GOLDBERG, JEROME D

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 12/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/753,472

Applicant(s)

INDIG, GUILHERME LUIZ

Examiner

Jerome D Goldberg

Art Unit

1614

-- The MAILING DATE of this communication appears in the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-14 is/are pending in the application.
- 4a) Of the above claim(s) 1-5 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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Claims 6-10 and 12-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific cancers disclosed, does not reasonably provide enablement for the term "cancer cells". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The term "cancer cells" in claims 6-10 and 12-14 lacks clear exemplary support forth the reasons fully set forth in paper no. 8, pages 2 and 3.

Applicant's remarks are noted, but Indig declaration only tested human colon adenocarcinomas cells, human uterine sarcoma cells and multiple drug resistant human uterine sarcoma cells. The specification only tested leukemia cells. Clearly, those limited number of cancers will not support the broad term "cancer cells".

Claims 7-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "in vitro" in claim 7, "in vivo" in claim 8, and "ex vivo" in claim 9 fail to find ^{basis} ~~basis~~ in claim 6 as amended.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over the indig (1999) or the indig et al. (2000). The Indig (1999) reference teaches that "the

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triarylmethanes appear to as to constitute one of the most promising series " (page 13, col, 2, lines 21-22) and shows crystal violet as one of the triarylmethanes (page 13).

The reference further states, " the combination of light and a photosensitizing agent for selective destruction of neoplastic tissue represents a new modality of cancer treatment known as photodynamic therapy. This review highlights basic features of the mechanisms of action of photosensitizers in vivo", including dyes of the triarylmethane family (page 9, col. 1, abstract). The reference " in addition, their systemic toxicity is apparently low and those already tested in vitro displayed significant phototoxicity towards malignant cells "(page 18, col. 1, lines 1-3). The Indig et al, reference (page 88, abstract, lines 7-9) states that " we report that the triarylmethane dye crystal violet stain cell mitochondrion with efficiency and selectivity, and is a promising candidate for photo chemotherapy application. Crystal violet exhibits pronounced photo toxicity towards L 1210 leukemia cells". The references do not teach the in vivo activity of the dyes as claimed along with the time limits the exposed to light. Accordingly, one skilled in this art would find ample motivation from the prior art supra to employ the crystal violet with light in photo chemotherapy in vivo against cancer including leukemia with a reasonable expectation that said crystal violet would be effective in treating said cancer including leukemia. Clearly, a showing over the prior art is needed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner J. D. Goldberg whose telephone number is (703) 308-4606. The examiner can normally be reached on Monday through Thursday from 9:00 A.M. to 3:00 P.M.

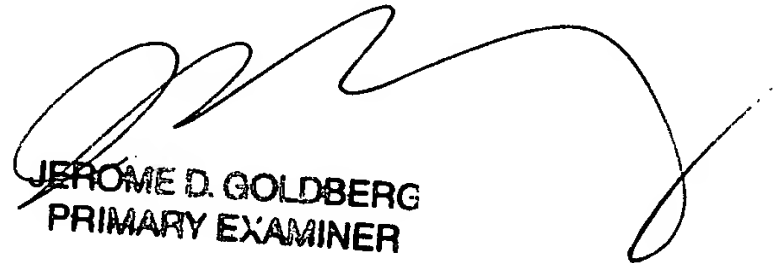
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications or (703) 305-3592 for after communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Goldberg//T.G.D
December 19, 2002.



JEROME D. GOLDBERG
PRIMARY EXAMINER